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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,791	04/05/2001	Lee Harland	PCS10914ADAM	4080

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Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159, Eastern Point Road
Groton, CT 06340

EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/11/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/826,791	HARLAND, LEE	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 22-33* is/are pending in the application.

4a) Of the above claim(s) *31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 22-30* is/are rejected.

7)☒ Claim(s) *6 and 31-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Claims 1-2 and 4-6 have been amended, claims 7-21 have been cancelled and claims 23-26 have been added as requested in the amendment of Paper No. 10, filed on September 25, 2002. Claims 1-6 and 22-33 are pending in the instant application.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on September 25, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claim 2 stands rejected under 35 U.S.C. 112, first paragraph essentially for those reasons of record as applied to claims 1-3 and 22 in section 9 of Paper No. 7.

Claims 2 is directed to a polynucleotide, wherein the compliment of said polynucleotide hybridizes to the full length coding sequence of a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2 or SEQ ID NO: 6 or a polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1 or SEQ ID NO: 5, wherein said polynucleotide encodes a G-protein coupled receptor (GPCR). However, the instant specification describes only one embodiment that is PFI-017, a leukotriene receptor, identified by SEQ ID NOS: 1, 2, 5 and 6. The instant specification fails to disclose how to use any other molecular embodiments that are functional

GPCR. Therefore, one skilled in the art clearly would not know how to use the claimed invention, which is any polynucleotide that hybridizes to the compliment of the described polynucleotide under moderate stringency conditions.

The instant specification discloses that a polynucleotide encoding the amino acid sequence presented in SEQ ID NO:2 or 6 of the instant specification can be employed to produce a naturally occurring cell surface receptor which is a member of the G protein-coupled receptor family. The protein encoded thereby can be used to identify ligands in addition to leukotrienes, which may be potentially pharmacologically relevant. The information derived therefrom is only relevant in so far as it is applicable to the native protein. Because the genetic code is well known in the art an artisan can readily make and use any polynucleotide encoding a protein comprising the disclosed amino acid sequence.

However, because the instant specification does not identify those amino acid residues in the amino acid sequence of SEQ ID NO:2 or 6, which are essential for biological activity and structural integrity and those residues which are either expendable or substitutable, a practitioner can not make and use a polynucleotide which encodes a polypeptide lacking all or a specific part of that sequence. In the absence of such structure-function information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis of over 300 amino acid residues before they could even begin to rationally design a polynucleotide encoding a functional leukotriene receptor polypeptide having other than a natural amino acid sequence.

One skilled in the art readily recognizes that a polynucleotide that can hybridize under moderate stringency conditions to the compliment of the polynucleotides of SEQ ID NO:1 or 5

of the instant specification does not necessarily have to be identical to the polynucleotides of SEQ ID NO: 1 or 5. Consequently, a polypeptide, which is encoded by such polynucleotide, can also show some deviations from polypeptides of SEQ ID NO: 2 or 6 in its amino acid structure. However, it is well know in the art that substitution of even one amino acid could leads to a different protein by definition, and can lead to a total alteration of properties of a protein (see Introduction to Proteins and Protein Engineering, 1986, Elsevier, p.41). The instant specification only discloses how to use a polypeptide of SEQ ID NO: 2 or 6 and does not disclose how to use any other protein, which does not function in a manner that is representative of its native analog. The disclosure of a DNA sequence encoding one protein with a natural amino acid sequence is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for a claim, which encompasses a polynucleotide that lacks the disclosed sequence and encodes a GPCR.

6. Claims 1-6, 23 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 27 are indefinite for recitation of "moderate" and " high" stringent hybridization conditions for reasons of record as applied to claim 1 in section 13 of Paper No. 7. Applicant argues that the conditions of hybridization are recited on page 24 of the instant specification. However, the recited conditions are exemplarily or "typical" (page 24, line 19), which means that the conditions recited in the claim or specification are not defined. Recitation of precise conditions in the claims would avoid this ground of rejection.

8. Claims 2-6, 23 and 28-33 are indefinite for being dependent from the indefinite claim.

New grounds of rejection and objection necessitated by amendment

Claim Objections

9. Claims 31-33 are objected to under 37 CFR 1.75(c) as being in improper form because multiple dependent claims 31-33 depend from multiple dependent claim 30. See MPEP § 608.01(n). Accordingly, claims 31-33 is not been further treated on the merits.

10. Claims 1-6 and 22-30 are under examination in the instant office action.

11. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 6 depends from claims 4 or 5, which are limited to nucleic acids encoding a protein, while claim 23 encompasses a membrane preparation of a cell. Therefore, claims 4 and 5 can be infringed by a nucleic acid, which does not infringe claim 6. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the instant case, the nucleic acid claims could be infringed without infringing the claims from which it depends, i.e. the protein claims. Therefore, they are improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 112

12. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 4 is directed to a host cell transformed or transfected with a vector comprising a polynucleotide of claim 1, said host cell expresses a polypeptide of SEQ ID NO: 2 or 6. However, claim 1 is not limited to a polynucleotide, which encodes a polypeptide of SEQ ID NO: 2 or 6, see claim 1, part (e). Therefore, one skilled in the art clearly would not know how to produce a host cell using a vector comprising a compliment to the polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1 or 5, said cell expressing a polypeptide of SEQ ID NO: 2 or 6. It would require undue experimentation and making a substantial inventive contribution in order to practice Applicant's invention, as currently claimed.

13. Claims 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 5 is vague and confusing for recitation of "a polypeptide fragment". It is not clear what polypeptide and what fragment are intended by the claim.

15. Claims 23 and 28 provides for the use of "said polynucleotide", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23 and 28 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

16. Claims 29-30 are vague and indefinite for recitation of "further comprising" or "further comprises". It is unclear if a polynucleotide encompassed by the claims is suppose to comprise additional sequences or additional properties. Clarification is required.

Double Patenting

17. Applicant is advised that should claims 1 and 2 be found allowable, claims 29-30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

18. Claims 29-30 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 24-25. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

19. Claims 1-6, 23 and 27-30 are rejected. Claims 22 and 24-26 are allowable.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
December 10, 2002 OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1600